

EXHIBIT 497

1 UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION
4

5 -----x
6 IN RE: NATIONAL PRESCRIPTION) Case No.
7 OPIATE LITIGATION) 1:17-MD-2804
8 APPLIES TO ALL CASES) Hon. Dan A. Polster
9 -----x

10
11 HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER
12 CONFIDENTIALITY REVIEW
13 VIDEOTAPED DEPOSITION OF MICHAEL R. CLARKE

14 SANDSTON, VIRGINIA

15 FRIDAY, DECEMBER 7, 2018

16 9:13 A.M.
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24 Reported by: Leslie A. Todd

1 recall the specific, you know, back and forth.

2 And then at some point, one of these
3 conversations mentioned putting together or
4 expanding this working group -- because it may
5 have existed already; they asked me to join. When
6 they explained what it was that we were trying to
7 do in terms of suspicious orders and the DEA
8 regulation, and, you know, I said, I'm happy to
9 pitch in, happy to help.

10 Q Who was John -- you just mentioned John
11 LaRocca. What was his role at Actavis?

12 A I believe John LaRocca was the senior
13 lawyer or general counsel for the Americas, which
14 was a division of Actavis that I worked for at the
15 time.

16 Q Did you report directly to him?

17 A Since I had gotten involved with this,
18 I'm trying to recall if I reported to John or
19 reported to Doug Boothe, and I just don't recall.
20 I mean John signed my hiring letter, but I don't
21 think I reported to John.

22 Q Doug Boothe was the CEO, correct?

23 A I believe CEO and president of Actavis
24 Americas.

1 Q And you did not report to John Duff; is
2 that right?

3 A Oh, I did not report to John Duff.

4 Q Were you --

5 A We were colleagues.

6 Q Were you in the same working group, same
7 organizational group?

8 A I mean John was legal; I was compliance.
9 So our offices were two doors down from each other
10 and we were colleagues. So...

11 Q Okay. You mentioned recalling generally
12 conversations with John Duff or John LaRocca about
13 joining the effort to -- joining the suspicious
14 order monitoring group or having some
15 responsibility regarding suspicious order
16 monitoring, right?

17 A Yeah. I had maybe one or two
18 conversations with John LaRocca, and then I had
19 more conversations with John Duff about joining
20 this working group, working team.

21 Q Other than just the prospect of joining
22 the group and being asked to join the group, do
23 you recall any of the content generally of those
24 discussions?

1 A No.

2 Q You don't recall whether there was any
3 commentary about the suspicious order monitoring
4 system in place not being up to snuff?

5 A No.

6 Q The final bullet point under -- the
7 final bullet point with any text under "Legacy
8 Actavis Beginnings" states: "Use of ValueTrak
9 Safe and Secure program to monitor retail level
10 purchases."

11 A I see that.

12 Q Do you know what ValueTrak Safe and
13 Secure program is? Do you recall what that is?

14 A I don't recall specifically. It was
15 some sort of data tool, but beyond that, I can't
16 tell you.

17 Q Who would be best positioned to talk
18 about what the ValueTrak Safe and Secure data tool
19 was?

20 A Whatever individuals were managing or
21 operating the ValueTrak Safe and Secure system,
22 but I don't know who that was. I really don't
23 recall.

24 Q Okay. And it mentions that that program

1 was used to monitor retail level purchases.

2 A That's what I wrote.

3 Q Do you recall how that tool was used
4 to -- to monitor retail level purchases?

5 A I really don't recall at this point.

6 Q Do you know what information that tool
7 monitored concerning retail level purchases?

8 A I mean I may have known back then, but I
9 don't recall at this point.

10 Q Do you know who at Actavis made use of
11 that information, the information being the retail
12 level purchases measured by the ValueTrak Safe and
13 Secure program?

14 A Whoever the employers at the operational
15 level that managed the ValueTrak system would
16 know, but I don't recall who those were.

17 Q You've referenced the operational level
18 a couple of times. I just want to make sure I
19 understand what you're talking about.

20 A Okay.

21 Q So can you describe what the operational
22 level or operations side of the company is when
23 you're using it in this instance?

24 A I mean, I think of in operations as -- I

1 mean, you can think of it as a structural thing or
2 an employee level thing. So, you know, I'm a
3 lawyer, I'm in compliance. I'm in shared
4 services; I'm a support function. If I was in
5 sales or marketing or manufacturing, and I was the
6 person who was operating the machines or who was
7 interacting with the physicians, that's more of an
8 operational function. You know, operational
9 transaction, doing the things that, you know --
10 but I -- I don't do those sort of things. I'm not
11 a salesperson. I'm not a machine operator. I'm
12 not even a machine operator supervisor or
13 that's -- when I say "operational," it's just who
14 was actually doing certain work versus a support
15 person or someone who is overseeing or managing or
16 giving guidance.

17 Q So you under- -- so the division -- and
18 I'm not trying to put words in your mouth. If
19 this is incorrect, just tell me it's wrong.

20 A Mm-hmm.

21 Q You understood your role and the role of
22 your peers to be looking at establishing guidance
23 for the way operations carried out certain of --
24 certain of its tasks?

1 A At best.

2 Q What do you mean "at best"?

3 A I mean, it wouldn't be -- we wouldn't go
4 beyond that. I -- you know, I wouldn't, you know,
5 be telling -- I wouldn't tell, you know, the
6 operational folks what to do in terms of specific
7 data analysis or things like that beyond just,
8 This may be what the law requires, this may be
9 what the regulation requires, and then I might
10 talk to the managers to say, Make sure that
11 whatever they do is consistent with law and
12 regulation and policy.

13 Q The next header on Exhibit 4 is labeled
14 "DEA Meetings." Do you see that?

15 A Yes.

16 Q Do you see the first bullet point says:
17 "D.C. meeting with SOM team in September 2012."

18 A Yes.

19 Q Do you recall that meeting?

20 A I do.

21 Q Did you attend that meeting?

22 A I did.

23 Q And D.C. is Washington, D.C., correct?

24 A Yes.

1 Q Do you recall who attended that meeting?
2 All of the -- as many attendees as you can
3 remember and where they were from.

4 A Well, all I could tell you is out in the
5 Actavis side, I was there, John Duff was there, I
6 believe Nancy Baran was there. I know there were
7 probably -- I think there were four or five of us
8 on the Actavis side, and I'm missing one or two
9 names, someone more operational was probably
10 there. But I believe there were four or five of
11 us on the Actavis side.

12 On the DEA side, they had people -- and
13 I don't remember the names of anyone on the DEA
14 side, but there were -- it was like a two-part
15 meeting, meaning that there were folks on -- there
16 were two women I remember who dealt with quotas,
17 manufacturing quotas, and they were there either
18 at the very beginning or the very end. You know,
19 so that was part 1 or part 2 of the meeting. But
20 the bulk of the meeting dealt with the, I guess,
21 the folks on the enforcement unit. There were
22 three or four of them there, but there was only
23 two people talking.

24 Q For quotas, you're talking about quotas

1 for the manufacture and sale of certain drugs?

2 A Certain controlled drugs, yes.

3 Q Certain controlled drugs.

4 Do you recall the purpose of this
5 meeting?

6 Well, let's start out, do you recall who
7 requested this meeting? Whose idea was it?

8 A Well, the DEA requested the meeting.

9 Q Do you recall why they requested it? Do
10 you have an understanding of why?

11 A I don't know why they requested it
12 because I wasn't in those discussions. I just
13 know we received a request from the DEA to meet
14 with us. I guess someone scheduled it, it was set
15 up, and then the Actavis folks went down.

16 Q Other than the government side, the
17 individuals in different government agencies and
18 the individuals from Actavis, was there anybody
19 else in attendance at the meeting?

20 A I know -- I believe we had talked about
21 whether we should bring counsel, but -- if it
22 was -- I believe we did, I just don't remember
23 specifically, but we decided not to. I don't
24 think there was a need for it.

1 So on the Actavis side, it was just
2 internal Actavis folks, from what I remember. And
3 then, like I said, different divisions or
4 departments within the DEA, the enforcement folks
5 and then the quota folks.

6 Q It was just a bilateral meeting between,
7 generally speaking, the DEA side and the Actavis
8 side; is that correct?

9 A That's what I remember, yes.

10 Q Do you recall the purpose of the meeting
11 generally?

12 A I think as a general matter, it was a
13 meeting for -- ostensibly for the DEA to talk to
14 us about our anti-diversion efforts.

15 Q And you say "ostensibly." Why -- why do
16 you qualify it in that way?

17 A I qualify it that way based on how the
18 meeting went, the tone and the tenor of the
19 meeting, meaning that it was less productive than
20 it could have been, and it could have -- the
21 purpose to discuss anti-diversion efforts could
22 have been achieved in a different way, with a
23 different tone and a different type of
24 presentation, and looking and talking to us as --

1 who were on the manufacturing side, as
2 professionals as opposed to street dealers.

3 Q Am I correct -- reading between the
4 lines of your answer, am I correct that the DEA
5 was critical of Actavis's anti-diversion efforts
6 in that meeting?

7 MR. LUXTON: Objection.

8 THE WITNESS: I wouldn't put it that
9 way. I think -- the way I looked at it -- the
10 way -- and, you know, we talked afterwards. It
11 wasn't so much as just being critical of our
12 anti-diversion efforts. The undertone of the
13 meeting was an implicit criticism of the fact that
14 we were making these products in the first place,
15 and we were -- and when I say "we," I mean Actavis
16 was at that meeting, but they referred to one or
17 two other companies that were also making generic
18 opioid products as not being responsible. And in
19 a sense that they described it, without using
20 these specific words, but in a way that we would
21 just manufacture, put the product out on the
22 street, and not have a care as to where it went.

23 Because they described their efforts
24 at -- you know, whatever enforcement efforts they

1 were engaged in, they described finding or seeing
2 or obtaining product, you know, opioid products
3 that seemed to be diverted relatively easily, I
4 guess is the way to describe it.

5 So it was -- you know, and they were
6 haranguing us about certain things. So it just
7 was not the most productive conversation about
8 anti-diversion efforts, about manufacturing of
9 these products, things like that.

10 BY MR. MELAMED:

11 Q You mentioned that they mentioned -- the
12 DEA mentioned during this meeting one or two other
13 manufacturers of generic opioids, correct?

14 A Yes.

15 Q Do you recall who they -- who the DEA
16 mentioned?

17 A I know they mentioned more than one, but
18 Mallinckrodt was one name that came up that I
19 recall.

20 Q And you don't recall any other names?

21 A I don't remember at this point.

22 Q Do you see the sub-bullet point --
23 returning to Exhibit 4, the sub-bullet point that
24 says: "Discussion of likely diversion of

1 oxycodone in FL and other high risk states"?

2 A Yes.

3 Q FL stands for Florida, right?

4 A That's right.

5 Q Do you recall which other high risk
6 states were discussed?

7 A I believe -- I mean, the discussions
8 seemed to focus mostly on the East Coast. So it
9 was Florida, I remember that specifically, and
10 they spent most of the time on Florida, so the
11 other states were almost secondary, tertiary.
12 They might have mentioned Virginia or West
13 Virginia. I know they mentioned other states, but
14 I -- I would be guessing, and I don't want to do
15 that. I don't recall specifically.

16 Q Do you remember whether the DEA had
17 anything to say about Actavis's suspicious order
18 monitoring program during that meeting?

19 A Yeah, I mean, ultimately the discussion
20 came over to that because, you know, that's what
21 we were prepared -- the Actavis team was prepared
22 to talk about. And without knowing -- because I'm
23 not sure if there was an agenda, without knowing,
24 you know, a list we're going to, you know, talk --

1 discuss these items or these topics, we came
2 prepared to talk about our SOM program.

3 We may have had a presentation deck that
4 we were either going to give or present on a
5 screen. I don't recall the logistics, but I know
6 we were prepared to talk about that, and we had a
7 deck prepared to go through and explain what it
8 was that we were doing, and hopefully engage in a
9 dialogue about whether -- you know, to what extent
10 we were -- you know, we believed we were meeting
11 the requirements of the CSA and the SOM
12 regulations, if there was any concern that the DEA
13 had about whether we were not going far enough in
14 certain regards, we could make adjustments. We
15 were hoping to have that type of dialogue, that
16 these are the things that we're doing. We think
17 it meets or exceeds the standards of the law and
18 the regulations.

19 And as the DEA, as the enforcement
20 agency, responsible for this, we would hope that
21 they would give us some level of guidance,
22 informal, at a meeting to say, you know, That's
23 great, that's fine, maybe you can do this better.
24 We were looking for that sort of interchange, and

1 it wasn't that.

2 Q You mentioned a PowerPoint deck that was
3 prepared by Actavis for purposes of this meeting,
4 correct?

5 A I believe we brought it down with us. I
6 know there was a PowerPoint that we used
7 internally, and I believe that we modified it to
8 present to the DEA.

9 Q Were you involved in the creation or
10 modification of that PowerPoint --

11 A I was involved in the modification of
12 that PowerPoint. Sorry to interrupt.

13 Q No, I didn't finish.
14 PowerPoint deck was what I was going to
15 say.

16 Do you recall what it was named?

17 A I don't recall what it was named.

18 Q Okay. And you don't recall whether it
19 was actually provided to or presented to the DEA
20 during that September meeting?

21 A I feel like it was given to them in some
22 fashion. I just don't recall specifically whether
23 we e-mailed it to them, gave them a hard copy or
24 something else, but I know we were prepared to